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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540
30766	7590	04/06/2006	EXAMINER	
DEWIPAT INCORPORATED 4606 FM 1960 WEST, SUITE 400, PMB 166 HOUSTON, TX 77069			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/657,446	Applicant(s) EDGREN ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 10 January 2006.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 46,48,51 and 53-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 46,48,51 and 53-60 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 and request for extension of time, amendment and remarks, all filed 1/10/06. Claims 46, 48, 51, 53-60 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 1/10/06 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 46, 48, 51 and 53-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,558,879).

Chen discloses a controlled release dosage form comprising a core of medicament and pharmaceutically acceptable excipients and polymeric binders and osmotic agents. The core is coated with a dual membrane coating where the dual membrane consists of first inner coating layer and a second outer coating layer. See abstract. A 24-hour therapeutic blood level is achievable with this dosage form (column 3, lines 59-64). The inner coating layer consists of plasticized water insoluble pharmaceutically acceptable polymer and a pharmaceutically

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acceptable water-soluble polymer; the second outer coating consists of a medicament and water-soluble polymer (abstract). Water-insoluble polymers applicable in Chen are cellulose esters, cellulose ethers, cellulose acylate cellulose acetate, cellulose diacetate, ethylcellulose and cellulose ethyl ether. Hydroxypropylmethyl cellulose, hydroxypropyl cellulose or cellulose may be combined with the water insoluble polymer to modify the permeability of the membrane coat around the core (column 5, lines 1-20 and column 6, lines 6-56). The application does not exclude medicine from the outer membrane coat layer. The dosage of Chen would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Chen reads on the claimed dosage form. The teachings of Chen meet the limitations of the claims.

4. Claims 46, 48, 51 and 53-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248).

Bartoo teaches an osmotic dosage form comprising an outside wall and an inside wall (abstract). The outside wall comprises semipermeable polymers where the semipermeable polymers are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate and cellulose diacetate and triacetate (column 3, line 54 to column 4 line 5). The inside wall comprises polymeric formulation that is responsive to environmental changes such as pH (column 4, lines 6-9). The internal compartment comprises beneficial agents or active drugs and the dosage form also has an expandable layer (column 4, lines 47-68 and column 7, line 6). In example 1, the cores are coated with an inside wall forming composition comprising hydroxypropylmethylcellulose phthalate, cellulose acetate, sorbitol and polyethylene glycol; and the second outside semipermeable wall is coated onto to the inside wall. The scope of the claims in the application read broadly on a conventional osmotic dosage form and reads on

Bartoo. The dosage of Bartoo would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Bartoo reads on the claimed dosage form. The claimed method is a broad administration of the claimed composition and Bartoo's dosage form is administered to animals. Osmotic dosage form contain osmotic core. Thus, Bartoo anticipates the claims.

Response to Arguments

Applicants argue with respect to Bartoo that the instant specification lists PEG as a material that can be included in the first membrane and cites Example 1 and Figure 5 of the instant specification to support the position.

With regards to Chen, applicants state that Chen does not teach semipermeable composition.

5. Applicants' arguments filed 1/10/06 have been fully considered but they are not persuasive.

Regarding Bartoo, it is noted that Bartoo discloses semipermeable membrane and it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding Chen, it is noted that the polymers of Chen present in the coating layer are the same polymers as claimed and thus would be semipermeable even though, Chen has not used the language of semipermeable. Chen inherently discloses semipermeable layer.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

